DOCKET NO.: UPAP-0497/H-1257

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Weiner, D.B. et al.,

Serial No.: 10/076,900

Filing Date: February 14, 2002 **Examiner: Not Yet Assigned**

METHODS FO INDUCING MUCOSAL IMMUNITY

DATE OF DEPOSIT:

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231.

OBJIGINALLY FILED COPY OF PAPERS

Group Art Unit: Not Yet Assigned

TYPED NAME: Mark DeLuca **REGISTRATION NO.: 33,229**

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

図 In accordance with §1.97(b), since this Information Disclosure Statement is being

filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first office action after the filing of request for continued examination under §1.114, no additional fee is required.

DOCKET N	IO.: UPAP-0497/H-1257 - 2 - PATENT		
	In accordance with §1.129(a), this Information Disclosure Statement is being		
	filed in connection with \square the first or \square second After Final Submissi		
	therefore:		
	☐ Certification in Accordance with §1.97(e) is attached; or		
	The fee of $$180.00$ as set forth in $$1.17(p)$ is attached.		
	In accordance with §1.97(c), this Information Disclosure Statement is being filed		
	after the period set forth in §1.97(b) above but before the mailing date of either		
	a Final Action under §1.113 or a Notice of Allowance under §1.311, or before ar		
	action that otherwise closes prosecution in the application, therefore:		
	☐ Certification in Accordance with §1.97(e) is attached; or		
	☐ The fee of \$180.00 as set forth in §1.17(p) is attached.		
	In accordance with §1.97(d), this Information Disclosure Statement is being filed		
•	after the mailing date of either a Final Action under §1.113 or a Notice of		
	Allowance under §1.311 but before, or simultaneously with, the payment of the		
	Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and		
	the submission fee of \$180.00 as set forth in §1.17(p).		
	Copies of each of the references listed on the attached Form PTO-1449 are		
	enclosed herewith.		
	Copies of references listed on the attached Form PTO-1449 are enclosed herewith		
	EXCEPT THAT:		
	☐ In view of the voluminous nature of references [list as appropriate], and		
	the likelihood that these references are available to the Examiner, copies		
	are not enclosed herewith.		

- In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C.§120 have been made in the instant application:
- Copies of references **AA thru CR** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 08/357,398, filed **December 16, 1994**.
 - If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date:

3/14/02

Mark DeLuca

Registration No.33,229

WOODCOCK WASHBURN LLP One Liberty Place - 46th Floor Philadelphia, PA 19103 Telephone: (215) 568-3100

Facsimile: (215) 568-3439

© 2001 WW



OBIGINALLY FILED COPY OF PAPERS

Sheet 1 of 8

Form PTO-1449 Modified

List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce Patent and Trademark Office Docket No. **UPAP-0497/H-1257**

Serial No. **10/076,900**

Applicant Weiner et al.

Filing Date February 14, 2002

Group

Not yet assigned

U. S. PATENT DOCUMENTS

		T. T				
Examiner		Document	Date	Name	Class	Subclass
	AA	4,224,404	09/23/80	Viza et al.	435	2
	AB	4,394,448	7/19/83	Szoka, Jr. et al.	435	172
	AC	4,806,463	02/21/89	Goodchild et al.	435	5
	AD	4,945,050	07/31/90	Sanford et al.	435	172.1
	AE	5,017,487	05/21/91	Stunnenberg etal	435	172.3
	AF	5,036,006	07/30/91	Sanford et al.	435	170.1
	AG	5,264,618	11/23/93	Felgner, et al.	560	224
	AH	5,593,972	01/14/97	Weiner, et al.	514	44
	AI	5,589,466	12/96	Felgner, et al.	514	44
	AJ	6,214,804	04/01	Felgner, et al.	514	44
	AK	5,679,647	10/21/97	Carson, et al.	514	44
	AL	5,185,254	02/09/93	Linnenbach	435	172.3

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES NO
	AM	WO 90/11092	10/4/90	PCT/US90/01515	xx
	AN	WO 91/12329	08/22/91	PCT/US91/00941	xx
	AO	WO 93/17706	09/16/93	PCT/US93/02338	xx
	AP	WO 93/23552	11/25/93	PCT/US93/04831	xx
	AQ	WO 94/16737	8/4/94	PCT/US94/00899	xx
EVANTATION					

EXAMINER

DATE CONSIDERED



Sheet 2 of 8

Form PTO-1449 Modified		Docket No. UPAP-0497/H-1257	Serial No. 10/076,900	
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Weiner et al.		
		nt of Commerce ademark Office	Filing Date February 14, 2002	Group Not yet assign d
OTHER DOC	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			nent Pages, Etc.)
	AR	Acsadi et al., "Huma After Intramuscular 352: 815-818 (1991)		
	AS	Anderson, W. French, "Prospects for Human Gene Therapy," Science 226:401-409, 1984.		nan Gene Therapy,"
	АТ	Benoit et al., "Destruction and regeneration of skeletal muscle after treatment with a local anaesthetic, bupivacaine (Marcaine®)," J. Anat. 107:547-556, 1970		
	UA	Benvenisty et al., "Direct introduction of genes into rats and expression of the genes," Proc. Natl. Acad. Sci. USA, 83:9551-9555, 1986		
,	AV	Brandsma et al., "Use of induce papillomas by cont the E7 gene is required," 1991	ttontail rabbit papilloma	avirus DNA shows that
	WA	Brigham et al., "Rapid Co Lungs with a Functioning American Journal of the I	Prokaryotic Gene Using A	A Liposome Vehicle,"
	AX	Butini, L. et al., "Comparative Analysis of HIV-Specific CTL Activity in Lymphoid Tissue and Peripheral Blood" J. of Cell Biochem. Suppl 18B: 147 (Abstract J306 (1994)		
	AY	Dubensky et al., "Di plasmid DNA into the Natl. Acad. Sci. USA	e liver of spleen of	mice," Proc.

EXAMINER	DATE CONSIDERED
<u></u>	1



OBIGINALLY FILED

Sheet 3 of 8

	-\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	TRANCES OF		Sheet 3 of 8
	PTO	-1449 Modified	Docket No. UPAP-0497/H-1257	Serial No. 10/076,900
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Weiner et al.	*	
		at of Commerce demark Office	Filing Date February 14, 2002	Group Not yet assigned
OTHER DOCUM	MENT	'S (Including Author,	Title, Date, Perti	nent Pages, Etc.)
1	AZ	Felgner and Rhodes, 352 (1991)	"Gene Therapeutics"	Nature 349: 351-
I	BA	Fleckenstein et al., oncogenic primate he		
E	вв	Friedmann et al., "F Science, 244:1275-12		n Gene Therapy,"
E	вс	Hall-Craggs, E.C.B., "Rapid Degeneration and Regeneration of a Whole Skeletal Muscle Following Treatment with Bupivacain (Marcain)," Experimental Neurology, 43:349-358, 1974		
E	BD	Haynes, B.F., "Scient Immunodeficiency Vir 1279-1286 (1993)		
E	BE	Howley, Peter M., "Replication," Virolo		
F	BF	Israel et al., "Biol in Mice and Hamsters		-
I	BG	Kaneda et al., "Incr with Nuclear Protein 243:375-378, 1989	_	

EXAMINER	DATE CONSIDERED



Sheet 4 of 8

FORM PTO-1449 Modified

Docket No. UPAP-0497/H-1257

Serial No. 10/076,900

List of Patents and Publications
Cited by Applicant
(Use several sheets if necessary)

Applicant Weiner et al.

U.S. Department of Commerce Patent and Trademark Office Filing Date

February 14, 2002

Group
Not yet assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

OTHER DOC	UMEN	rs (Including Author, Title, Date, Pertinent Pages, Etc.)
	вн	Klein et al., "Transformation of Microbes, Plants and Animals by Particle Bombardment," Bio/Technology, 10:286-291, 1992
	BI	Knuth, A. et al., "Cellular and Humoral Immune Responses Against Cancer:Implications for Cancer Vaccines" Current Opinion in Immunology 3: 659-664 (1991)
·	вЈ	Ledley, F.D., "Clinical Considerations in the Design of Protocols for Somatic Gene Therapy" Human Gene Therapy 2: 77-83 (1991)
	вк	Mayne et al., "Tumour Induction by Simian Adenovirus SA7 DNA Fragments," Nature New Biology, 232:182-183, 1971
	BL	McCutchan et al., "Enhancement of the Infectivity of Simian Virus 40 Deoxyribonucleic Acid with Diethylaminoethyl-Dextran," J. of the Nat. Cancer Institute, 41:351-356, 1968
	вм	Nabel et al., "Site-Specific Gene Expression in Vivo by Direct Gene Transfer into the Arterial Wall," Science, 249:1285-1288, 1990
	BN	Nicolau et al., "In vivo expression of rat insulin after intravenous administration of the liposome-entrapped gene for rat insulin I," Proc. Natl. Acad. Sci. USA, 80:1068-1072, 1983
	во	Orth et al., "Infectious and Oncogenic Effect of DNA Extracted from Cells Infected with Polyoma Virus," P.S.E.B.M., 115:1090-1095, 1964

EXAMINER	DATE CONSIDERED



Sheet 5 of 8 Form PTO-1449 Modified Docket No. Serial No. UPAP-0497/H-1257 10/076,900 List of Patents and Publications Cited by Applicant Applicant (Use several sheets if necessary) Weiner et al. U.S. Department of Commerce Filing Date Group Patent and Trademark Office February 14, 2002 Not yet assigned OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) BP Sol et al., "Oncogenicity of SV40 DNA in the Syrian Hamster," J. gen. Vir. 37:635-638, 1977 Tang et al., "Genetic immunization is a simple method BQ for eliciting an immune response," Nature 356:152-154, Thomason et al., "Stable incorporation of a bacterial BR gene into adult rat skeletal muscle in vivo, " Cell Physiol., 27:C578-581, 1990 Torpey, III, D. et al., "Effects of Adoptive Immunotherapy with BS Autologous CD8 T Lymphocytes on Immunologic Parameters: Lymphocyte Subsets and Cytotoxic Activity" Clinical Immunology and Immunopathology 68(3): 263-272 (1993) Ulmer et al., "Heterologous Protection Against Influenza BT by Injection of DNA Encoding a Viral Protein," Science, 259:1745-1749, 1993 Vitadello et al., "Gene Transfer in Regenerating BU Muscle, " J. of Cellular Biochemistry, Suppl. 17E:252, March 29-April 25, 1993 Wang, B. et al.,, "Gene Innoculation Generates Immune BVResponses Against Human Immunodeficiency Virus Type 1" Proc. Natl. Acad. Sci. USA 90: 4156-4160 (1993) Wells, D.J., "Improved Gene Transfer by Direct Plasmid BW Injection Associated with Regeneration in Mouse Skeletal Muscle" FEBS Letts 332(1,2) 179-182 (1993)

EXAMINER	DATE CONSIDERED
	SHIE CONDIDERED



Sheet 6 of 8

\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		1400	Sheet 6 of 8	
1	TO-1449 Modified	Docket No. UPAP-0497/H-1257	Serial No. 10/076,900	
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Weiner et al.		
U.S. Departm Patent and T	ent of Commerce rademark Office	Filing Date February 14, 2002	Group Not yet assigned	
OTHER DOCUME	NTS (Including Author,	Title, Date, Perti	nent Pages, Etc.)	
BX	Will et al., "Cloned chimpanzees," Nature			
ВУ	Wolff et al., "Direction Vivo" Science 247: 1	ct Gene Transfer int 1465-1468 (1990)	o Mouse Muscle in	
BZ	Wolff et al., "Condi Into Rodent Muscle I (1991)	Wolff et al., "Conditions Affecting Direct Gene Transfer Into Rodent Muscle In Vivo" <i>BioTechniques 11:</i> 474-485 (1991)		
CA	Wu et al., "Receptor expression in Vivo," 263:14621-14624, 198	Wu et al., "Receptor-mediated Gene Delivery and expression in Vivo," J. of Biological Chemistry, 263:14621-14624, 1988		
СВ	Yang et al., "In vivo and in vitro gene transfer to mammalian somatic cells by particle bombardment," Proc. Natl. Acad. Sci. USA, 87:9568-9572, 1990			
cc	Zelenin et al., "High-velocity mechanical DNA transfer of the chloramphenicolacetyl transferase gene into rodent liver, kidney and mammary gland cells in organ explants and in vivo," FEBS Letts., 280:94-96, 1991			
CD	Fynan, E.F. et al., Hemagglutinin as an Biol., 1993, 12(9),	avian influenza vac	g influenza cine", DNA Cell	
CE	Staats, H.F. et al., implications for vac Immunol., 1994, 6, 5	cine development",	to infection with Curr. Opin.	

EXAMINER	DATE CONSIDERED



Sheet 8 of 8

EXAMINE	<u> </u>		1	DATE CONSIDEREI			
	CR	WO 96/14876	05/23/96	PCT	X		
	CQ	WO 94/23738	10/27/94	PCT	X		
	СР	WO 94/17792	08/18/94	PCT	X		
Examiner Initial		Document No.	Date	Country	Tr: YES	Translation YES NO	
		FORI	EIGN PATENT	T DOCUMENTS			
Examiner Initial		Document No.	Date	Name	Class	Subclass	
		U.	S. PATENT I	OCUMENTS			
U.S. Department of Commerce Patent and Trademark Office				Filing Date February 14, 200	Group Not yet assigned		
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)				Applicant Weiner et al.			
	Form PTO-1449 Modified			Docket No. UPAP-0497/H-1257	Docket No. UPAP-0497/H-1257 Serial No. 10/076,900		



Creation date: 09-08-2003

Indexing Officer: ESPRICIGO - ELIZABETH SPRICIGO

Team: OIPEBackFileIndexing

Dossier: 10076900

Legal Date: 04-19-2002

Total number of pages: 6

No.	Doccode	Number of pages
1	CRFL	6

Remarks:
Order of re-scan issued on